

Express Mail Label: EV306257334US
PATENT

ATTORNEY DOCKET: D0968-00044

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Peter J. Cronk; Kristen Cronk

Serial No.: not assigned

Filed: Herewith

For: Adhesively Applied External Nasal Strips and dilators Containing
Medications and Fragrances

CERTIFICATION UNDER 37 CFR § 1.10

EXPRESS MAIL LABEL NO: EV306257334US

I hereby certify that this correspondence and the documents referred to as attached therein are being deposited with the U.S. Postal Service in an envelope as "EXPRESS MAIL POST OFFICE TO ADDRESSEE" service under 37 CFR § 1.10, Mailing Label Number as listed above, addressed to U.S. Patent and Trademark Office, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Date September 30, 2003
By Mary La Grange

MS: Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

INFORMATION DISCLOSURE STATEMENT TRANSMITTAL LETTER

Enclosed herewith is an Information Disclosure Statement pursuant to 37 CFR. § 1.56 in connection with the above-identified application, which statement is being filed:

☒ [X] Together with the present application.

☐ [] Before the first Office Action on the merits or three (3) months from the filing date of this application, whichever occurs last. [37 CFR § 1.97(b)]

☐ [] After the first Office Action on the merits, but before a Final Office Action under §1.113 or Notice of Allowance under §1.311, whichever occurs first. [37 CFR §1.97(c)]. (Either the fee or certification is provided, as set forth below).

☐ [] After a Final Office Action under §1.113 or Notice of Allowance under §1.311, but prior to or with payment of the Issue Fee. [37 CFR §1.97(d)]. The fee and certification are provided, as set forth below).

Consistent with Applicant's obligations pursuant to 37 CFR §§1.97 and 1.98, the following requirements have been met:

☒ No separate requirements are needed.

☒ No additional fee is required.

Fee Under 37 CFR § 1.97(c) or 1.97(d)

☐ The fee of \$180.00 for submission of an IDS under § 1.97(c) as set forth in § 1.17(p) accompanies this statement.

Certification Under 37 CFR § 1.97(e)

The undersigned certifies:

☐ 1 that each item of information contained in the information disclosure statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or

☐ 2 that no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in §1.56(c) more than three months prior to the filing of the information disclosure statement.

Provision of Copies of References

☐ A copy of each of the references listed on the attached Form PTO-1449 is enclosed herewith and forms a part hereof.

☐ A translation of Reference _____ is enclosed herewith and forms a part hereof.

☐ A copy of the European Search Report from a corresponding or related EPO application is enclosed herewith.

☐ A copy of the International Search Report from a corresponding or related PCT application is enclosed herewith.

Identification of Prior Application(s) In Which Listed Information Was Already Cited And For Which No Copies Are Submitted Or Need Be Submitted

[X] This application relies, under 35 U.S.C. § 120, on the earlier filing date of prior U.S. Patent Application No. Serial No. 10/859,319, filed May 17, 2001, which is a continuation of application Serial No. 09/099, 825, filed June 18, 1998, which is a continuation-in-part of application Serial No. 08/942,797, filed October 2, 1997, which is a continuation of application Serial No. 08/791,760, filed January 29, 1997, now U.S. Patent No. 5,706,800. All of the references were submitted to, and/or cited by, the Office in the prior application(s) and therefore are not required to be provided in this application:

[X] The Commissioner is hereby authorized to charge any fees associated with this communication or credit any overpayment to Deposit Account No. 04-1679.

Date: 9.30.03

Respectfully submitted,



Peter J. Cronk

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| Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i> Sheet 1 of 8 | ATTY. DOCKET NO. D0968-00044 | APPLICATION NO. Not yet assigned |
| | FIRST NAMED APPLICANT Cronk, Peter J. | EXAMINER Not yet assigned |
| | FILING DATE Herewith | GROUP Not yet assigned |

U.S. PATENT DOCUMENTS

| EXAMINER INITIALS | Cite No. | DOCUMENT NUMBER | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear |
|----------------------|-------------|-----------------|---|--|--|
| | A | 5,720,966 | 2/24/98 | Ostendorf | |
| | B | D310,565 | 9/90 | Petruson | |
| | C | 35,408 | 12/96 | Petruson | |
| | D | 35,408 | 12/96 | Petruson | |
| | E | 3,464,413 | 9/2/69 | Goldfarb et al. | |
| | F | 3,567,118 | 3/71 | Shepherd et al. | |
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| | H | 3,688,985 | 9/72 | Engel | |
| | I | 3,710,799 | 1/73 | Caballero | |
| | J | 3,846,404 | 11/74 | Nichols | |
| | K | 3,909,444 | 9/75 | Anderson et al. | |
| | L | 3,954,963 | 5/76 | Kuderna, Jr. | |
| | M | 3,965,033 | 6/76 | Matsukawa et al. | |
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| | X | 4,386,135 | 5/31/83 | Campbell et al. | |
| | Y | 4,414,977 | 11/83 | Rezakhany et al. | |

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| Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i> Sheet 2 of 8 | ATTY. DOCKET NO. D0968-00044 | APPLICATION NO. Not yet assigned |
| | FIRST NAMED APPLICANT Cronk, Peter J. | EXAMINER Not yet assigned |
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| EXAMINER INITIALS | Cite No. | DOCUMENT NUMBER | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear |
|----------------------|-------------|-----------------|---|--|--|
| | Z | 4,487,801 | 12/11/84 | Turnbull et al | |
| | AA | 4,492,644 | 1/85 | Matsumoto et al. | |
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| | AC | 4,528,226 | 7/9/85 | Sweeny | |
| | AD | 4,597,959 | 7/86 | Barr | |
| | AE | 4,638,043 | 1/87 | Szycher et al. | |
| | AF | 4,654,256 | 3/31/87 | Doree et al. | |
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| Substitute for form 1449/APTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i> Sheet 3 of 8 | ATTY. DOCKET NO. D0968-00044 | APPLICATION NO. Not yet assigned |
| | FIRST NAMED APPLICANT Cronk, Peter J. | EXAMINER Not yet assigned |
| | FILING DATE Herewith | GROUP Not yet assigned |

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| | AZ | 5,175,152 | 12/92 | Singh | |
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| | BI | 5,476,091 | 12/95 | Johnson | |
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| Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i> Sheet 4 of 8 | ATTY. DOCKET NO. D0968-00044 | APPLICATION NO. Not yet assigned |
| | FIRST NAMED APPLICANT Cronk, Peter J. | EXAMINER Not yet assigned |
| | FILING DATE Herewith | GROUP Not yet assigned |

| EXAMINER INITIALS | Cite No. | DOCUMENT NUMBER | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear |
|----------------------|-------------|-----------------|---|--|--|
| | BX | 5,706,800 | 1/98 | Cronk et al. | |
| | BY | 5,711,941 | 1/98 | Behan et al. | |
| | BZ | 5,720,966 | 2/98 | Ostendorf | |
| | CA | 5,723,420 | 3/98 | Wei et al. | |
| | CB | 5,725,865 | 3/98 | Mane et al. | |
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| | CG | 6,244,265 | 6/12/01 | Cronk et al. | |
| | CH | 6,276,360 | 8/21/01 | Cronk et al. | |
| | CI | 6,295,982 | 10/2/01 | Reed, Jr. | |

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| EXAMINER INITIALS | Cite No. | Office | DOCUMENT NUMBER | COUNTRY | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear | T |
|----------------------|-------------|--------|-----------------|----------|--|---|---|
| | CJ | | WO 98/57613 | 23.12.98 | PCT | x | |
| | CK | | WO 98/32403 | 30.07.98 | PCT | x | |
| | CL | | WO 92/22340 | 23.12.92 | PCT | X | |
| | CM | | WO92/14607 | 3SEP92 | PCT | X | |
| | CN | | WO98/57613 | 23DEC98 | PCT | X | |
| | CO | | WO93/13938 | 22JUL93 | PCT | X | |
| | CP | | WO95/26155 | 5OCT95 | PCT | | X |
| | CQ | | EPO195254A | 24SEP86 | EPO | X | |
| | CR | | JP10120555A | 5/12/98 | Japan | abstract | |
| | CS | | JP7048250A | 2/21/95 | Japan | abstract | |
| | CT | | JP7215847A | 8/15/95 | Japan | abstract | |

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| Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i> Sheet 5 of 8 | ATTY. DOCKET NO. D0968-00044 | APPLICATION NO. Not yet assigned |
| | FIRST NAMED APPLICANT Cronk, Peter J. | EXAMINER Not yet assigned |
| | FILING DATE Herewith | GROUP Not yet assigned |

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|--|----|--|-----------------|---------|-----|---|--|
| | CU | | WO98/27897 | 7/2/98 | PCT | x | |
| | CV | | EP 1 033 118 A1 | 6/9/00 | EPO | x | |
| | CW | | WO98/06360 | 2/19/98 | | | |
| | | | | | | | |

OTHER DOCUMENTS

| Examiner Initials | Cite No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date page(s), volume-issue number(s), publisher, city and/or country where published. | T |
|-------------------|----------|---|---|
| | CX | Written Opinion dated 13 JUN 2002 | |
| | CY | International Search Report dated 2 June 2000 | |
| | CZ | CNS, Inc. prospectus dated March 29, 1996 (highlighted page 25) | |
| | DA | Buchbauer G., Jirovetz L., Jaeger W., Plank C., Dietrich H., Title "Fragrance Compounds and Essential Oils with Sedative Effects Upon Inhalation", Source: Journal of Pharmaceutical Sciences 82 (6), 1993, pgs. 660-664. (Abstract only) | |
| | DB | Nagahara A., Benjamin H., Storkson J., Krewson J., Sheng K., Liu W., Pariza M., Title "Inhibition of Benzo-A-Pyrene-Induced Mouse Forestomach Neoplasia by a Principal Flavor Component of Japanese-Style Fermented Soy Sauce", Source: Cancer Research 52 (7), 1992, pgs. 1754-1756. (Abstract only) | |
| | DC | Halim A.F., Mashaly M.M., Sandra P., Title "Constituents of the Essential Oil of Mentha-Microphylla C.Koch.", Source: Egyptian Journal of Pharmaceutical Sciences 31 (1-4), 1990, pgs. 437-442. (Abstract only) | |
| | DD | Jungnickel P.W., Shaefer M.S., Maloley P.A., Campbell J.R., Shawaryn G.G., Goris G.B., Oliphant T.H., Title "Blind Comparison of Patient Preference for Flavored Colestid Granules and Questran Light", Source: Annals of Pharmacotherapy 27 (6), 1993, pgs. 700-703. (Abstract only) | |
| | DE | Ognyanov I., Fam Thi Bin Min, Todorova M., Kuleva L., Title "Chemotypes in Some Bulgarian Populations of Chrysanthemum-Vulgare L. Bernh.", Source: Comptes Rendus de L'Academie Bulgare des Sciences 45 (4), 1992, pgs. 29-31. (Abstract only) | |
| | DF | Schaller M., Korting H.C., Title "Allergic Airborne Contact Dermatitis from Essential Oils Used in Aromatherapy", Source: Clinical & Experimental Dermatology 20 (2), 1995, pgs. 143-145. (Abstract only) | |
| | DG | Mukhtar H., Katiyar S.K., Agarwal R., Title "Green Tea and Skin-Anticarcinogenic Effects", Source: Journal of Investigative Dermatology 102 (1), 1994, pgs. 3-7. (Abstract only) | |

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| Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i> Sheet 6 of 8 | ATTY. DOCKET NO. D0968-00044 | APPLICATION NO. Not yet assigned |
| | FIRST NAMED APPLICANT Cronk, Peter J. | EXAMINER Not yet assigned |
| | FILING DATE Herewith | GROUP Not yet assigned |

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| | DH | Everett T., Dennis M., Ricketts E., Title "Physiotherapy in Mental Health: A Practical Approach", Source: Everett T., M. Dennis and E. Ricketts (Ed.) Physiotherapy in Mental Health: A Practical Approach. xv+424p. Butterworth-Heinemann Ltd., London, England, UK; Butterworth-Heinemann: Newton, Massachusetts, USA. XV+424P. ISBN 0-7506-1700-4. 1995. (Abstract only) | |
| | DI | Komori T., Fujiwara R., Tanida M., Nomura J., Yokoyama M.M., Title "Effects of Citrus Fragrance on Immune Function and Depressive States", Source: Neuroimmunomodulation 2(3), 1995, pgs. 174-180. (Abstract only) | |
| | DJ | Lis Balchin, Hart S., Title: A Preliminary Study of the Effect of Essential Oils on Skeletal and Smooth Muscle in Vitro", Source: Journal of Ethnopharmacology 58(3), 1997, pgs. 183-187. (Abstract only) | |
| | DK | Lindsay W.R., Pitcaithly D., N. Buntin., L. Broxholme, S. Ashby M., Title "A Comparison of the Effects of Four Therapy Procedures on Concentration and Responsiveness in People with Profound Learning Disabilities", Source: Journal of Intellectual Disability Research 41 (3), 1997, pgs. 201-207. (Abstract only) | |
| | DL | Morice A.H., Marshall A.E., Higgins K.S., Grattna T.J., Title "Effect of Inhaled Menthol on Citric Acid Induced Cough in Normal Subjects", Source: Thorax 49 (10), 1994, pgs. 1024-1026. (Abstract only) | |
| | D M | Eccles R., Griffiths D.H., Newton C.G., Tolley N.S., Title "The Effects of Menthol Isomers on Nasal Sensation of Airflow", Source: Clinical Otolaryngology & Allied Sciences (Oxford) 13 (1), 1988, pgs. 25-30. (Abstract only) | |
| | DN | Zaenker K.S., Toelle W., Bluemel G., Probst J., Title "Evaluation of Surfactant-Like Effects of Commonly Used Remedies for Colds", Source: Respiration 39 (3), 1980, pgs. 150-157. (Abstract only) | |
| | DO | Cohen B.M., Dressler W.E., Title: "Acute Aromatics Inhalation Modifies the Airways Effects of the Common Cold", Source: Respiration 43 (4), 1982, pgs. 285-293. (Abstract only) | |
| | DP | Eccles R., Jones A.S., Title "The Effect of Menthol on Nasal Resistance to Air Flow", Source: Journal of Laryngology & Otology 97 (8), 1983, pgs. 705-709. (Abstract only) | |
| | DQ | Burrow A., Eccles R., Jones A.S., Title "The Effects of Camphor Eucalyptus and Menthol Vapor on Nasal Resistance to Air Flow and Nasal Sensation", Source: Acta Oto-Laryngologica 96 (1-2), 1983, pgs. 157-162. (Abstract only) | |
| | DR | Gal Fuzy M., Szente L., Szejtli J., Harangi J., Title "Cyclodextrin-Stabilized Volatile Substances for Inhalation Therapy", Source: Pharmazie 39 (8), 1984, pgs. 558-559. (Abstract only) | |
| | DS | Khadzhai Ya I., Bashura G.S., Sheherbakova N.R., Aslanyants A.A., Kuznetsova V.F., Title "The New Aerosol Preparation Camphomene", Source: Khimiko-Farmatsevticheskii Zhurnal 11 (1), 1977, pgs. 147-149. (Abstract only) | |

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| Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i> Sheet 7 of 8 | ATTY. DOCKET NO. D0968-00044 | APPLICATION NO. Not yet assigned |
| | FIRST NAMED APPLICANT Cronk, Peter J. | EXAMINER Not yet assigned |
| | FILING DATE Herewith | GROUP Not yet assigned |

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| DT | Robinson M.K., Cruze C.A., Title "Preclinical Skin Sensitization Testing of Antihistamines: Guinea Pig and Local Lymph Node Assay Responses", Source: Food & Chemical Toxicology 34 (5), 1996, pgs. 495-506. (Abstract only) | |
| DU | Radler S., Blaschek G., Title "Transdermal Absorption of Dimethindene in Man.", Source: Archiv der Pharmazie (Weinheim) 328 (2), 1995, pgs. 127-129. (Abstract only) | |
| DV | Binger Str., Title "Accumulation of Granulocytes in the Lung and Skin of Guinea Pigs: Inhibition by the Anti-H-1 Antiallergic Agent Epinastine", Source: Arzneimittel-Forschung 44 (12), 1994, pgs. 1338-1342. (Abstract only) | |
| DW | Harada S., Takahashi Y., Nakagawa H., Title "Transdermal Administration of Emedastine", Source: Biological & Pharmaceutical Bulletin 16 (9), 1993, pgs. 884-888. (Abstract only) | |
| DX | Robinson M.K., Parsell K.W., Breneman D.L., Cruze C.A., Title "Evaluation of the Primary Skin Irritation and Allergic Contact Sensitization Potential of Transdermal Triprolidine", Source: Fundamental & Applied Toxicology 17 (1), 1991, pgs. 103-119. (Abstract only) | |
| DY | Miles M.V., Balasubramanian R., Pittman A.W., Grossman S.H., Pappa K.A., Smith M.F., Wargin W.A., Findlay J.W.A., Poust R.J., Frosolono M.F., Title "Pharmacokinetics of Oral and Transdermal Triprolidine", Source: Journal of Clinical Pharmacology 30 (6), 1990, pgs. 572-575. (Abstract only) | |
| DZ | B. Petruson, Title: "Two New Ways for Nasal Administration of Drugs with the Nasal Dilator Nozovent", Source: ENT-Department, University of Götterborg, Sahlgren's Hospital, 413 45 Göteborg, Sweden | |
| EA | "Breathe Right" Nasal Strips, Manufactured by CNS, Inc., Chanhassen, MN | |
| EB | Article entitled "New Device Offers Relief for Snorers" | |
| EC | Hornung et al., "Effect of Nasal Dilators on Perceived Odor Intensity", Chem. Senses 22:177-180, April 1997 | |
| ED | Hornung et al., "Effect of Nasal Dilators on Olfaction: I Nasal Structure and Sniffing Strategies", pp 1-8, unpublished | |
| EE | Hornung et al., "Effect of Nasal Dilators on Olfaction: II Threshold, Intensity and Identification", pp 1-7, unpublished | |
| EF | 3M-CNS, Inc., Distribution Agreement dated August 2, 1995 | |
| EG | Letter from Ronald S. Spangleer, Ph.D (Managing Director of Emerging Growth Equities, LLC) to Richard E. Jahnke (CNS, Inc.) dated August 27, 1996 | |
| EH | Memo from John Neveaux (JLN Associates) to Andy Anderson dated October 30, 1992 | |

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| Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i> Sheet 8 of 8 | ATTY. DOCKET NO. D0968-00044 | APPLICATION NO. Not yet assigned |
| | FIRST NAMED APPLICANT Cronk, Peter J. | EXAMINER Not yet assigned |
| | FILING DATE Herewith | GROUP Not yet assigned |

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|---|--|-----------------|
| EI | Letter from Daniel E. Cohen, M.D. (Chairman & CEO of CNS, Inc.) to Ronald S. Spangler, Ph.D (Emerging Growth Equities, LLC) dated September 9, 1996 | |
| EJ | Kleenex® Cold Care™ with Menthol box (copyright notice 1986 and 1996) | |
| EK | Zheng G.Q., Kenney P.M., Zhang J., Lam L.K.T., Title "Inhibition of Benzo-A-Pyrene-Induced Tumorigenesis by Myristicin A Volatile Aroma Constituent of Parsley Leaf Oil", Source: Carcinogenesis (Eynsham) 13 (10), 1992, pgs. 1921-1923. (Abstract only) | |
| EL | Teopista N., Title "The Use of Aroma Therapy A.T. in the Management of People with Aids PWAS", Source: IXth International Conference on Aids and the IVth Std. World Congress. IXth International Conference on Aids in Affiliation with the IVth Std. World Congress" Meeting, Berlin, Germany, June 6-11, 1993. 649P. IXth International Conference on Aids: Berlin, Germany, 1993, 497. (Abstract only) | |
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| EXAMINER | | DATE CONSIDERED |
| EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant. | | |